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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,389	07/18/2001	Hitoshi Endou	55562	8159
21874	7590	03/22/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			PAK, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/786,389	<b>Applicant(s)</b> ENDOU ET AL.	
	<b>Examiner</b> Michael Pak	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>see attachment 2 pages</u> .           |

**DETAILED ACTION**

***Response to Amendment***

1. Amendment filed December 29, 2005 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed December 29, 2005, have been fully considered but they are not found persuasive.
4. Claims 1-4 pending. Claims 5-59 have been cancelled.

***Claim Rejections - 35 USC § 101***

5. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that the transport of amino acids into cells and medical research provide substantial utility for the claimed invention referencing page 6 of the specification. However, animals contain many different types transporters for which the medical significance is not clear. Page 6 does not provide the nexus between the claimed transporter and diseases or treatments.

Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 2 recites "substances similar thereto" which is new matter because the disclosure could not be found in the specification and the applicant did not point to where in the specification the support for the new claim limitation is located.

Claim 1 recites "wherein 1 to 40 amino acid residues are substituted, deleted or added" which is new matter because the disclosure could not be found in the specification and the applicant did not point to where in the specification the support for the new claim limitation is located.

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Claim 1 recites "amino acid sequence selected from one or more of:" which is new matter because the disclosure could not be found in the specification and the applicant did not point to where in the specification the support for the new claim limitation is located. The specification does not disclose multiple sequence cell surface protein of SEQ ID NO:2 and 4.

***Claim Rejections - 35 USC § 102***

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaugitsch et al. (JBC, 1992 (AL)).

The reason for the rejection was set forth in the previous office action.

Gaugitsch et al. disclose a protein which has 100% amino acid sequence identity with the claimed SEQ ID NO:2 (see attached sequence comparison). The protein inherently has the function of the the transporter and interaction with other proteins such as 4F2hc proteins.

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Pak  
Primary Examiner  
Art Unit 1646  
March 15, 2006

GenCore version 5.1.6  
Copyright (c) 1993 - 2004 CompuGen Ltd.

OM protein - protein search, using sw model

Run on: November 17, 2004, 14:19:00 ; Search time 27.3651 Seconds  
(without alignments)  
1782.634 Million cell updates/sec

Title: US-09-786-389C-2  
Perfect score: 2602  
Sequence: 1 MAGAGPKRRALAAPAEKE.....GIFSTTVLCQKLMQVVPQEST 507

Scoring table: BLOSUM62  
Gapop 10.0 , Gapext 0.5

Searched: 283416 seqs, 96216763 residues  
Total number of hits satisfying chosen parameters: 283416

Minimum DB seq length: 0  
Maximum DB seq length: 2000000000  
Post-processing: Minimum Match 0%  
Maximum Match 100%  
Listing first 45 summaries

Database : PIR\_79:\*

1: pir1:\*

2: pir2:\*

3: pir3:\*

4: pir4:\*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	ID	Description
1	2602	100.0	507	JG0165	LAT1 protein - hum
2	1207.5	46.4	493	2 T21445	hypothetical prote
3	1060	40.7	563	2 T32479	hypothetical prote
4	986	37.9	464	2 T28818	hypothetical prote
5	658.5	25.3	541	2 T31554	hypothetical prote
6	651.5	25.0	566	2 T15226	hypothetical prote
7	634.5	24.4	562	2 T16854	hypothetical prote
8	525	20.2	455	2 A11995	amino acid transpo
9	523	20.1	440	2 T24837	hypothetical prote
10	507.5	19.5	662	2 T32821	hypothetical prote
11	488	18.8	440	2 B89921	hypothetical prote
12	486.5	18.7	438	2 B69855	amino acid permeas
13	406	15.6	424	2 B69172	cationic amino aci
14	402	15.4	503	2 T34694	probable cationic
15	395	15.2	574	2 S61943	methionine transpo
16	371	14.3	463	2 A11513	amino acid transpo
17	362.5	13.9	462	2 B86002	probable amino aci
18	362.5	13.9	462	2 E91156	probable amino aci
19	361	13.9	463	2 A81155	amino acid transpo
20	360.5	13.9	462	2 E85131	hypothetical 47.5
21	357	13.7	461	2 D69814	metabolite transpo
22	351.5	13.5	483	2 C82587	cationic amino aci
23	347.5	13.4	546	2 D87396	amino acid permeas
24	339.5	13.0	476	2 A70704	probable rocE prot
25	335.5	12.9	463	2 A81383	amino acid transpo
26	335.5	12.9	463	2 A11758	amino acid transpo
27	323.5	12.4	465	2 E69825	amino acid transpo
28	322.5	12.4	477	2 D82587	cationic amino aci
29	311.5	12.0	467	2 A97985	hypothetical prote

30	311.5	12.0	736	2 C59451	cationic amino aci
31	305.5	11.7	589	2 T32785	hypothetical prote
32	305	11.7	509	2 G82809	amino acid transpo
33	304.5	11.7	463	2 E95115	amino acid permeas
34	304.5	11.7	583	2 T48473	amino acid transpo
35	303	11.6	438	2 F97234	ethanolamin permea
36	301.5	11.6	776	2 A84178	cationic amino aci
37	300	11.5	470	2 F71686	cationic amino aci
38	297.5	11.4	728	2 F84279	amino acid transpo
39	297	11.4	466	2 H97303	probable amino aci
40	293.5	11.3	616	2 C90355	amino acid transpo
41	291.5	11.2	590	2 A86307	amino acid transpo
42	291.5	11.2	622	2 A32742	murine ecotropic r
43	289	11.1	545	2 C90047	hypothetical prote
44	289	11.1	629	2 S29685	retroviral recepto
45	287.5	11.0	433	2 D87636	amino acid permeas

ALIGNMENTS

RESULT 1

JG0165

LAT1 protein - human

C:Species: Homo sapiens (man)

C>Date: 23-Jul-1999 #sequence\_revision 23-Jul-1999 #text\_change 09-Jul-2004

C:Accession: JG0165; A42783

R:D.Prasad, P.; Wang, H.; Huang, W.; Kekuda, R.; P. Rajan, D.; H. Leibach, F.; Ganapathy, R.; Biochem. Biophys. Res. Commun. 255, 283-288, 1999

A:Title: Human LAT1, a subunit of system L amino acid transporter: Molecular cloning an

A:Reference number: JG0165; MUID:99160855; PMID:10049700

A:Accession: JG0165

A:Status: preliminary

A:Molecule type: DNA

A:Residues: 1-507 <DAP>

A:CROSS-references: UNIPROT:Q01650; GB:AF104032; NID:G4426639; PIDN:AA35780.1; PID:G44

R:Gaigoltsch, H.W.; Prieschl, B.E.; Kalthoff, F.; Huber, N.E.; Baumruker, T.

J. Biol. Chem. 267, 11267-11273, 1992

A:Title: A novel transiently expressed, integral membrane protein linked to cell activa

A:Reference number: A42783; MUID:92283834; PMID:1597461

A:Accession: A42783

A:Status: preliminary

A:Molecule type: mRNA

A:Residues: 267-507 <GAU>

A:CROSS-references: GB:M80244; NID:G181907; PIDN:AAA35780.1; PID:G181908

A:Experimental source: peripheral blood lymphocytes

A:Note: sequence extracted from NCBI backbone (NCBIN:104749, NCBIP:104750)

C:Superfamily: arginine permease

C:Keywords: transmembrane protein

Query Match 100.0%; Score 2602; DB 2; Length 507;

Best Local Similarity 100.0%; Pred. No. 8.7e-187;

Matches 507; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 MAGAGPKRRALAAPAEKEEAREKMLAASADGSAPAGEGVTLQRLNLTLLNGVAIV 60

Db 1 MAGAGPKRRALAAPAEKEEAREKMLAASADGSAPAGEGVTLQRLNLTLLNGVAIV 60

QY 61 GTTIGSGIFVTPTGVLKEAGSPGLALVVAACGVFSIVGALCYAELGTTTISKSGGDYAYM 120

Db 61 GTTIGSGIFVTPTGVLKEAGSPGLALVVAACGVFSIVGALCYAELGTTTISKSGGDYAYM 120

QY 121 LEVVGSLPAFLKWIETLLIRPSSQYIVLVFATYLLKPLPTCPVPEAAKLVACLVL 180

Db 121 LEVVGSLPAFLKWIETLLIRPSSQYIVLVFATYLLKPLPTCPVPEAAKLVACLVL 180

QY 181 LLTAVNCYSVKAATRVQDAFAAAKLLALALLILGFVQIGKGDVSNLDPNFSFECKLDV 240

Db 181 LLTAVNCYSVKAATRVQDAFAAAKLLALALLILGFVQIGKGDVSNLDPNFSFECKLDV 240

QY 241 GNVILALYSGLFAYGGWNYLNFVTEEMINPYRNLPALIIISLPVITLVYVLTNLAYPTTL 300

Db 241 GNVILALYSGLFAYGGWNYLNFVTEEMINPYRNLPALIIISLPVITLVYVLTNLAYPTTL 300



09/786,389  
attached p 2

301 STEQMLSEAVADVDFGNVHGLVMSWIIIPVFGVLSGCVSGVNGSLFTSSRLPFVGSREGHLP 360  
301 STEQMLSEAVADVDFGNVHGLVMSWIIIPVFGVLSGCVSGVNGSLFTSSRLPFVGSREGHLP 360  
361 SILSMIHPQLLTVPVSLFTCVMTLLYAFSKDIFSVINFFSNWMLCVALLAIGMIWLH 420  
361 SILSMIHPQLLTVPVSLFTCVMTLLYAFSKDIFSVINFFSNWMLCVALLAIGMIWLH 420  
421 RKPELEPIKVNALPVPFFILACFLIAVSWFKTPVBCGFTIISGLPVYFGVWKN 480  
421 RKPELEPIKVNALPVPFFILACFLIAVSWFKTPVBCGFTIISGLPVYFGVWKN 480  
481 KPWLLQIGISTTVLCOKLMQVPOET 507  
481 KPWLLQIGISTTVLCOKLMQVPOET 507

RESULT 2  
T21445  
hypothetical protein F27C8.1 - Caenorhabditis elegans  
C:Species: Caenorhabditis elegans  
C:Date: 15-Oct-1999 #sequence\_revision 15-Oct-1999 #text\_change 09-Jul-2004  
C:Accession: T21445  
R:Lloyd, C.  
submitted to the EMBL Data Library, December 1995  
A:Reference number: Z19423  
A:Accession: T21445  
A:Status: preliminary; translated from GB/EMBL/DDBJ  
A:Molecule type: DNA  
A:Residues: 1-493 <WIL>  
A:Cross-references: UNIPROT:Q19834; EMBL:Z68216; PIDN:CAA92459.1; GSPDB:GN00022; CESP:F27C8  
A:Experimental source: clone F27C8  
C:Genetics:  
A:Gene: CESP:F27C8.1  
A:Map position: 4  
A:Introns: 60/1; 162/1; 204/1; 255/2; 385/3; 443/1; 474/1  
C:Superfamily: arginine permease

Query Match 46.4%; Score 1207.5; DB 2; Length 493;  
Best Local Similarity 48.9%; Pred. No. 1.2e-82;  
Matches 236; Conservative 91; Mismatches 149; Indels 7; Gaps 5;

30 KSADG-SAPAG--EGEGVTLQRTNITLLNGVAIVGTIIGSGIFVPTGVLKEAGSPGLAL 86  
9 KREGDEAPQNETGKGLKSLTLFNGVSMIVGCIIGSGIFVSPVQEOAGSVGLSL 68  
87 VVMAAGVPSIVGALCYAELGTITISKGGDYAMLEVYVGLSPAFKLWIELLIIRPSSQY 146  
69 IWLISGIIPTAGVYAEGLTILKSGGDYAYIMEAFGFVAFIRLWIEAIVVRPCTVT 128  
147 IVALVPATYLLKPLPPTCPVPEAAKLVAACLVLLTAVNCYSVKAATRVQDAFAAAKL 206  
129 IVALTFAIYGLRPFPPDCAPPDVAELLAIVLMTAINCISVRLATIVQDFIAKV 188  
207 ALALAIL--LGFVQVQKGDVSNLDPNPSFEGTKLDVGNIVLALYSGLPAYGWNVNFVT 264  
189 ALCLILTLGLLFFGSGYKDSFENI-FENISQDFTKVSFLAFYSGLFAYSGWNLNFTV 247  
265 EMINPYNPLPIAIIISLPITLVVLTNLAFTTLLSTEQMLSEAVADVDFGNVHGLVMS 324  
248 EELQNPKNLPLAIAISITCTVIVLTNVALYTAISPEMLSEAPAVLFAVANKLYGKFA 307  
325 WIIPVFGVLSGCVSGVNGSLFTSSRLPFVGSREGHLP SILSMIHPQLLTVPVSLFTCVMT 384  
308 FIMPLCAVSTIGSANGVIFTSARLFYSGAREGQMPAVLTINKKTKTPIPAVILTGALS 367  
385 LLYAF-SKDIQSVINFPFNNWMLCVALLAIGMIWLH RKPELEPIKVNALPVPFFILAC 443  
368 IAYLASKDQVQLINIQISYLAIGTAIALFVLRRTWPOASRDIPKVELIWPFAIFLAGC 427  
444 LFLIAVSPWKTPECGIFTIISGLPVYFGVWKNKPKWLLQIGISTTVLCOKLMQV 503

Db 428 IALVILPMVAAPRDTGIGILLIMLSAVPVYGIFGWMKNKPKWNEFIDSSTVFQKLFMVV 487  
QY 504 PQE 506  
Db 488 DED 490

RESULT 3  
T32479  
hypothetical protein F52H2.2 - Caenorhabditis elegans  
C:Species: Caenorhabditis elegans  
C:Date: 29-Oct-1999 #sequence\_revision 29-Oct-1999 #text\_change 09-Jul-2004  
C:Accession: T32479  
R:Chisoe, S.; Hawkins, J.  
submitted to the EMBL Data Library, September 1997  
A:Description: The sequence of C. elegans cosmid F52H2.  
A:Reference number: Z21175  
A:Accession: T32479  
A:Status: preliminary; translated from GB/EMBL/DDBJ  
A:Molecule type: DNA  
A:Residues: 1-563 <CHI>  
A:Cross-references: UNIPROT:O17395; EMBL:AF026214; PIDN:AAB71312.1; GSPDB:GN00028; CESP:F52H2  
A:Experimental source: strain Bristol N2; clone F52H2  
C:Genetics:  
A:Gene: CESP:F52H2.2  
A:Map position: X  
A:Introns: 20/3; 60/1; 123/2; 162/1; 204/1; 255/2; 296/3; 329/1; 401/2; 433/3; 544/1  
C:Superfamily: arginine permease

Query Match 40.7%; Score 1060; DB 2; Length 563;  
Best Local Similarity 40.1%; Pred. No. 1.5e-71;  
Matches 213; Conservative 90; Mismatches 154; Indels 74; Gaps 4;

46 LQRTITLLNGVAIVGTIIGSGIFVPTGVLKEAGSPGLALVMAACGVFSIVGALCYAE 105  
28 LKMTWLFNGSVIIGCIIGSGIFISPTGQAGSVGLSLIVVLSGLFAGIGAFCYAE 87  
106 LQTTISKGGDYAMLEVYVGLSPAFKLWIELLIIRPSSQYVALVFAVTLKPLPPTCP 165  
88 LGTLIRKSGDYAYIMEAFGFPLALWIESIVVRPCTATIVALTFAIMLKPFYPCDC 147  
166 VPBEAAKLVAACLVLLTAVNCYSVKAATRVQDAFAAAKLALALIIILGFVQIGKDV 225  
148 SPPLSTELIAALLVLLTAVNCISVKAASKVQDFFVTKTAALVLIIFGLWNNVSGKPE 207  
226 NLDPNFS--FEGTKLDVGNIVLALYSGIFAGVGNVLTNFTTEMINPYNPLPIAIIISLP 283  
208 AFD-SFENIFENTAKDLETASLAFYSGLFAYGWNVLTNFTTEMINPYNPLPIAIIISLP 266  
284 IVALVLTNLAFTTLLSTEQMLSEAVADVDFGNVHGLVMSWIIIPVFGVLSGCVSGV 343  
267 LCTIITLTNVALYTSITPDEMLASPAVALFAEKYGVWPAFCMFIIVACSTIGSANGVI 326  
344 FT----- 345  
327 LTRLCGRDVRQAAIAEVAEPQNPKEIFGNRLPNLTQKIFGNRLPFFENFVEIIFLS 386  
346 -----SSRLPFVGSREGHLP SILSMIHPQLLTVPVSLFTCVMTLLY-APSKD 392  
387 ALEKSMVFFPYSETLFCGAREGQMPNLTWNTKTKTPIPAVILTGLLSLLYLLSNN 446  
393 IFSVINFPFNNWMLCVALLAIGMIWLH RKPELEPIKVNALPVPFFILACFLIAVSWF 452  
447 IYSLINIQVSYNIAIGAILALFVFKTWDPADRAVAKAPIVFIIFIGCVLVLVPL 506  
453 KTPVECGIGFTIISGLPVYFGVWKNKPKWLLQIGISTTVLCOKLMQV 503  
507 GNPKDTAIGILLIMLSGVVYLIFIAWKGPKCIDSITDSTVIFTQKLFMVV 557

RESULT 4  
T28818  
hypothetical protein F07C3.7 - Caenorhabditis elegans